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10/605,537	10/06/2003	Noo Li Jeon	UC-P0001	2536

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EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 03/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/605,537

Applicant(s)

JEON ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2004 and 03 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-6, 10-13, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilding et al.(US 5,866,345).

With respect to claim 1, the reference of Wilding et al. discloses a microfluidic device that includes a first compartment (16) and a second compartment (16) coupled by a barrier region having micron-sized grooves (20) (See Figures 17a and 17b). Since the claim is devoid of any further positively recited structure and the grooves of the reference of the Wilding et al. are of micron size (See column 7, line 52, to column 8, line 28), the first compartment of Wilding et al. is considered to be capable of being fluidically isolated from the second compartment via hydrostatic pressure. Furthermore while the compartments are shown to be of the same volume they are capable of and/or are configured to a first volume of fluid and a second volume of fluid which is less than the first.

With respect to claims 2-5, in the absence of further positively recited structure, the compartments and grooves of the reference of Wilding et al. are considered to be capable of

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functioning in the intended manner recited in claims 2-5. Note statements of intended use carry no patentable weight in apparatus-type claims.

With respect to claim 6, in the absence of further positively recited structure, the microchannels or microgrooves (20) of the reference of Wilding et al. are considered to meet the claimed "patterned lines" limitation.

With respect to claim 10, the reference of Wilding et al. discloses that the substrate with the microchannels or microgrooves can be sealed to a glass substrate (See column 7, lines 38-51).

With respect to claims 11 and 16, the reference of Wilding et al. discloses the introduction of cells and a culture medium (cell body) within the device (See Example 4). If the cell body were a neuron then the groove present would provide a pathway for growing neuron processes.

With respect to claims 12-14, in the absence of further positively recited structure, the compartments and grooves of the reference of Wilding et al. are considered to be capable of functioning in the intended manner recited in claims 12-14. Note statements of intended use carry no patentable weight in apparatus-type claims.

With respect to claim 15, the reference of Wilding et al. discloses an inlet port in communication with chamber (16) (See Figures 1 and 3).

3. Claims 1-6, 11-13 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Kirk et al.(US 2002/0168757).

With respect to claim 1, the reference of Kirk et al. discloses a microfluidic device that includes a first compartment (13) and a second compartment (14) coupled by a region having micron-sized grooves (15) (See Figure 3A). Since the claim is devoid of any further positively recited structure and the grooves of the reference of the Kirk et al. are of micron size (See paragraph [0061]), the first compartment of Kirk et al. is considered to be capable of being fluidically isolated from the second compartment via hydrostatic pressure. Furthermore while the compartments are shown to be of the same volume they are capable of and/or are configured to a first volume of fluid and a second volume of fluid which is less than the first.

With respect to claims 2-5, in the absence of further positively recited structure, the compartments and grooves of the reference of Kirk et al. are considered to be capable of functioning in the intended manner recited in claims 2-5. Note statements of intended use carry no patentable weight in apparatus-type claims.

With respect to claim 6, in the absence of further positively recited structure, the microchannels or microgrooves (15) of the reference of Kirk et al. are considered to meet the claimed "patterned lines" limitation.

With respect to claims 11 and 16, the reference of Kirk et al. discloses providing one of the compartments with "a cell body" and fluid for maintaining the viability of the cells. If the cell body were a neuron then the groove present would provide a pathway for growing neuron processes.

With respect to claims 12-14, in the absence of further positively recited structure, the compartments and grooves of the reference of Wilding et al. are considered to be capable of

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functioning in the intended manner recited in claims 12-14. Note statements of intended use carry no patentable weight in apparatus-type claims.

4. Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Cremer et al. (US 2004/0005720).

With respect to claim 1, the reference of Cremer et al. discloses a microfluidic device that includes a first compartment (9) and a second compartment (10) coupled by a region having micron-sized grooves (4) (See Figures 1A or 3). Since the claim is devoid of any further positively recited structure and the grooves of the reference of the Cremer et al. are of micron size (See paragraph [0034]), the first compartment of Cremer et al. is considered to be capable of being fluidically isolated from the second compartment via hydrostatic pressure. Furthermore while the compartments are shown to be of the same volume they are capable of and/or are configured to a first volume of fluid and a second volume of fluid which is less than the first.

With respect to claims 2-5, in the absence of further positively recited structure, the compartments and grooves of the reference of Cremer et al. are considered to be capable of functioning in the intended manner recited in claims 2-5. Note statements of intended use carry no patentable weight in apparatus-type claims.

With respect to claim 6, in the absence of further positively recited structure, the microchannels or microgrooves (4) of the reference of Cremer et al. are considered to meet the claimed "patterned lines" limitation.

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5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al.(US 5,866,345).

The reference of Wilding et al. has been discussed above.

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With respect to claim 8, the reference of Wilding et al. discloses that the substrate with the microchannels or microgrooves can be sealed to a glass substrate (See column 7, lines 38-51). Claim 8 differs by reciting that the device is covalently bonded to glass via air plasma treatment.

In the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum manner in which to bond the microchannel substrate to the glass cover while maintaining a fluid-tight seal and maintaining the intended structural integrity of the device.

With respect to claim 9, the reference of Wilding et al. discloses that the device can be used to monitor reactions or cell culture growth (See column 7, lines 7-16).

In view of this teaching, it would have been obvious to employ the microchannel in combination with an art recognized culture substrate, such as a culture dish, for the known and expected result of providing the microchannel construction required of the reference of Wilding et al. while providing an art recognized substrate for maintaining, observing and/or compatible with the culture of cells.

9. Claims 7 and 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al. (US 5,866,345) in view of either Fedun (US 5,635,396) or Scott (US 5,773,222).

The reference of Wilding et al. has been discussed above.

Claims 7 and 14 differ by reciting that the device includes patterned lines of polylysine.

The reference of Wilding et al. discloses that the device can be used to monitor reactions or cell culture growth (See column 7, lines 7-16). The reference also discloses that it is known to chemically activate the detection channels (See column 9, lines 17-55).

The reference of Fedun discloses that the use of polylysine to enhance cell adhesion is known in the art of cell culture (See column 1, lines 23-33).

In view of these teachings, it would have been obvious to one of ordinary skill in the art to employ polylysine in the channels of the reference of Wilding et al. for the known and expected result of improving the adhesion of cultured cells within the channels when using the device to monitor a cell culture, as suggested by the reference of Wilding et al.

Alternatively, the reference of Wilding et al. discloses that the device can be used for a number of different types of assays including immunological assay and the reference also discloses that it is known to chemically activate the detection channels (See column 9, lines 17-55).

The reference of Scott discloses that it is known in the art to immobilize red cells on the surface of an immunoassay device using polylysine (See column 3, lines 9-15).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the channels of the reference of Wilding et al. with a polylysine for the known and expected result of providing an art recognized means for immobilization of immunoassay reagents within the channels of the device.

Response to Arguments

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10. Applicant's arguments filed 10/22/2004 have been fully considered but they are not persuasive.

11. With respect to the rejection of claims 1-6 under 35 USC 102 as being anticipated by Wilding et al., Applicants argue, see pages 6-8 of the response filed 10/22/2004, that the rejection is improper because the device of the reference of Wilding et al. is used to mix fluids together rather than separate fluids into distinct compartments.

In response, the Examiner is of the position that the rejection is proper for the following reasons:

i) The structure of the instantly claimed device and that of the reference of Wilding et al. are the same. As disclosed in the instant specification (See paragraphs [0037]-[0038]), the structure of the instant invention includes two chambers or compartments connected by a groove with dimensions in a micron range. The reference of Wilding et al. discloses a structure that includes two chambers or compartments (16) connected by a groove (20) with dimensions in a micron range (See Figures 1-4, 17A and 17B). In the absence of further positively recited structure, the structure disclosed by the reference of Wilding et al. is the same as that instantly claimed.

ii) In response to applicant's argument that the reference of Wilding et al. is used to mix fluids rather than separate fluids into distinct compartments, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim

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drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). In this case, if the structure of the device of Wilding et al. as discussed above were filled with a first volume of fluid and a second volume of fluid less than the first, the same hydrostatic pressure would result. As disclosed in the instant specification (See paragraph [0051]), the hydrostatic pressure is generated using a device that is structurally the same as that of Wilding et al.

iii) With respect to new claims 11 and 16, the reference of Wilding et al. discloses the use of cell bodies within the device. Note the instant claims merely recite that the first compartment or somal compartment comprises "a cell body". The claim does not specify that the cell body is a neuron.

12. With respect to the rejection of claims 1-6 under 35 USC 102 as being anticipated by Kirk et al., Applicants argue, see pages 7-8 of the response filed 10/22/2004, that the rejection is improper because the device of the reference of Kirk et al. is used to mix fluids together rather than separate fluids into distinct compartments.

In response, the Examiner is of the position that the rejection is proper for the following reasons:

i) The structure of the instantly claimed device and that of the reference of Kirk et al. are the same. As disclosed in the instant specification (See paragraphs [0037]-[0038]), the structure of the instant invention includes two chambers or compartments connected by a groove with dimensions in a micron range. The reference of Kirk et al. discloses a structure that includes two

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chambers or compartments (13,14) connected by a groove (15) with dimensions in a micron range (See Figure 3A and paragraph [0061]). In the absence of further positively recited structure, the structure disclosed by the reference of Kirk et al. is the same as that instantly claimed.

ii) In response to applicant's argument that the reference of Kirk et al. is used to mix fluids rather than separate fluids into distinct compartments, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). In this case, if the structure of the device of Kirk et al. as discussed above were filled with a first volume of fluid and a second volume of fluid less than the first, the same hydrostatic pressure would result. As disclosed in the instant specification (See paragraph [0051]), the hydrostatic pressure is generated using a device that is structurally the same as that of Kirk et al. Note the instant disclosure discloses that a flow of liquid between the compartments exists (See paragraph [0051]).

iii) With respect to new claims 11 and 16, the reference of Kirk et al. discloses the use of cell bodies within the device. Note the instant claims merely recite that the first compartment or somal compartment comprises "a cell body". The claim does not specify that the cell body is a neuron.

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13. With respect to the rejection of claims 1-6 under 35 USC 102 as being anticipated by Cremer et al., Applicants argue, see pages 9-11 of the response filed 10/22/2004, that the rejection is improper because the device of the reference of Cremer et al. is used to mix fluids together rather than separate fluids into distinct compartments.

In response, the Examiner is of the position that the rejection is proper for the following reasons:

i) The structure of the instantly claimed device and that of the reference of Cremer et al. are the same. As disclosed in the instant specification (See paragraphs [0037]-[0038]), the structure of the instant invention includes two chambers or compartments connected by a groove with dimensions in a micron range. The reference of Cremer et al. discloses a structure that includes two chambers or compartments (9, 10) connected by a groove (4) with dimensions in a micron range (See Figures 1A or 3). In the absence of further positively recited structure, the structure disclosed by the reference of Cremer et al. is the same as that instantly claimed.

ii) In response to applicant's argument that the reference of Cremer et al. is used to mix fluids rather than separate fluids into distinct compartments, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). In this case, if the structure of the device of Wilding et al. as discussed above were filled with a first volume of fluid and a second

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volume of fluid less than the first, the same hydrostatic pressure would result. As disclosed in the instant specification (See paragraph [0051]), the hydrostatic pressure is generated using a device that is structurally the same as that of Cremer et al.

14. With respect to the rejection of claims 7-9 under 35 USC 103 as being obvious over Wilding et al. in view of Fedun or Scott, Applicants argue, see page 11 of the response filed 10/22/2004, that the rejection is improper because the additional references fail to cure the deficiencies set forth with respect to the reference of Wilding et al.

In response, the additional references of Fedun and Scott were merely relied upon as tertiary references that addressed the further claim limitations of claims 7-9 and were not relied upon to meet the structure of the device recited in claim 1.

15. For the reasons advanced above, the rejection of the claims has been maintained.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period


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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


William H. Beisner
Primary Examiner
Art Unit 1744

WHB